Assessment of the relationship between patient and clinician ratings of swallowing function in individuals with head and neck cancer.

Dissertation

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Abstract

Dysphagia in patients with head and neck cancer (HNC) is a common adverse effect frequently seen within this population. To date there is no practical and reliable way of using subjective reports of swallowing to predict pathophysiology, measure airway safety impairments, or monitor progression of dysphagia. The purpose of this study was to determine the relationships between patient self-ratings of swallowing function using the Eating Assessment Tool (EAT-10), clinician ratings of oral intake using the Functional Oral Intake Scale (FOIS), physiologic measures of swallowing using the Modified Barium Swallow Impairment Profile (MBSImP), and airway safety during swallowing via the Penetration-Aspiration Scale (PAS) in individuals with HNC.

Patient self-rating scales of swallowing function and quality of life measures are routinely used for clinical decision-making and to determine when intervention is warranted. Though commonly used, it remains unknown if patient reports of the severity of swallowing difficulty and oral diet intake are associated with clinician measures of swallow dysfunction (pathophysiology and airway safety).

Forty-four patients with HNC participated in this study. Tumor locations included maxillary sinus, thyroid, oral cavity, oropharynx, pharynx and larynx. Treatment modalities included radiation, chemoradiation and surgery plus radiation, or chemoradiation. Participants at any stage in the continuum of cancer care were included in this study.
All participants completed the EAT-10 and underwent a modified barium swallow study (MBS). Participants’ oral intake was documented using the FOIS and MBSs were scored using the MBSImP.

Results showed moderate correlations between all outcome measures administered ($p < .05$). Consequently, this study suggests that the EAT-10 and FOIS can be used to monitor and document the progression of dysphagia throughout the continuum of care of a HNC patient. These outcome measures may assist health care providers with determining when intervention, including a MBS, is warranted. In addition, the correlations suggest that the EAT-10 and the FOIS may have relevance in both the clinical and research settings for this patient population.
Dedication

I dedicate this work to my husband, David Arrese. His love and support throughout this journey made it all possible.
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Chapter 1: Introduction

The presence or prior history of head and neck cancer (HNC) provides a unique challenge to the assessment and rehabilitation of swallowing function. Anatomical abnormalities of the head and neck region may result in detectable dysphagia and HNC is a major cause of anatomical abnormalities. Dysphagia within the HNC population may be secondary to mechanical effects of a tumor (mass effect), including invasion of the tumor into the anatomy needed for deglutition, neurosensory-related deficits (nerve involvement), tumor-related pain, or as a direct sequela of cancer treatment. All treatment modalities used to treat HNC, which include surgery and/or radiation therapy, either alone or in combination with chemotherapy (CRT), have been shown to leave functional deficits that prolong, produce, or magnify a swallowing problem (Lazarus, 1993; Smith, Kotz, Beitler, & Wadler, 2000).

Patient self-ratings of swallowing function and quality of life measures are routinely used for clinical decision-making, as well as for determining when assessments and interventions are warranted. It has been reported that individuals with HNC can perceive decrements in their swallowing function (Pauloski et al., 2002; Rogus-Pulia, Pierce, Mittal, Zecker, & Logemann, 2014) but it remains unknown if patient reports of severity correlate with clinicians’ objective measures of severity for this population. Two recent studies have examined the relationship between patient report via quality of life surveys and physiological
measures of swallowing function in individuals with HNC (Kendall, Kosek, & Tanner, 2014; Rogus-Pulia et al., 2014). Kendall and colleagues (2014) reported that quality of life ratings via the MD Anderson Dysphagia Inventory (Chen, Frankowski, Bishop-Leone, & et al., 2001) and The University of Washington Swallowing Quality of Life Questionnaire (Thomas et al., 2008) do not correlate with objective measures of swallowing physiology for this population (Kendall et al., 2014). They found no significant correlations between quality of life scores and individual measures of swallowing function across bolus volumes (1mL, 3 mL, 20 mL). The specific physiologic components of swallowing included in their analysis were: pharyngeal area, hyoid elevation, upper esophageal sphincter opening, and bolus transit time.

Rogus-Pulia and colleagues (2014) assessed the relationship between patient perception and physiological findings using a novel series of questions via a Likert-scale and found that patients who received chemoradiation therapy for HNC were able to recognize deterioration in swallowing function but lacked awareness of the specific symptoms related to their dysphagia (Rogus-Pulia et al., 2014). Specific measures of swallowing physiology included for analysis were: oral transit time, pharyngeal delay, pharyngeal response time, pharyngeal transit time, oral residue, and pharyngeal residue.

Both Kendall and colleagues (2014) and Rogus-Pulia and colleagues (2014) utilized the Modified Barium Swallow (MBS) to assess physiological components of swallowing. However, each study looked at novel aspects of physiological function.
Health-care professionals are faced with a population that has a high incidence of dysphagia, including impaired airway protection, with no reliable means to screen for changes in swallowing function and to determine when instrumental assessment via a MBS is warranted to assess safety and efficiency of swallowing. The MD Anderson Dysphagia Inventory (Chen et al., 2001) and The University of Washington Swallowing Quality of Life Questionnaire (Thomas et al., 2008) have been shown to have no significant correlation with pathophysiology of swallowing function. Other clinical outcome measures utilized as swallowing screening tools or as a means to document functional change include the Eating Assessment Tool (EAT-10) (Belafsky et al., 2008) and the Functional Oral Intake Scale (FOIS) (Crary, Mann, & Groher, 2005).

The EAT-10 (Belafsky et al., 2008) (Appendix A) is a symptom-specific, swallowing screening outcome instrument designed for patients to rate the degree of self-perceived swallowing impairments. It is reported to be a valid and reliable instrument to document dysphagia severity and monitor response to medical treatment for swallowing disorders. It is currently unknown how self-reports of swallowing function using the EAT-10 are associated with objective measures of swallow physiology, airway safety, or functional oral intake for individuals with HNC.

The FOIS (Crary et al., 2005) (Appendix B) is a 7-point ordinal scale indexing the amount and type of oral intake (food and liquid) an individual is able to consume. It is completed and scored by a health care provider based on medical chart review, dietary journals, or patient reports. Literature suggests that the FOIS is a reliable tool to document
change in the functional eating abilities of stroke patients (Crary et al., 2005). However, the FOIS is also commonly used in the clinical and research settings of HNC patients to track, document, and infer functional changes related to swallowing function (Bhatt et al., 2014; Crary, Carnaby, LaGorio, & Carvajal, 2012; Genden, Kotz, et al., 2011; Genden, Park, Smith, & Kotz, 2011; Kalavrezos et al., 2014; Kotz et al., 2012; Kraaijenga et al., 2014; Song et al., 2010; Starmer et al., 2014; Virani, Kunduk, Fink, & McWhorter, 2015).

As detailed below in Chapter 2, dysphagia is a common adverse effect frequently seen within the HNC population. To date, there is no practical and reliable way to predict pathophysiology, to detect airway safety impairments, or to monitor progression of dysphagia based on subjective reports of swallowing. The current project aimed to identify a tool that would highlight impairment, trigger the need for instrumental assessment, and monitor the effects of treatment for dysphagia within the HNC population. This study examined the relationship between patient self-ratings of swallowing function using the EAT-10, (Belafsky et al., 2008) and physiologic measures of swallowing using the MBSImP (Martin-Harris et al., 2008) in individuals with HNC. In addition, the relationships between the EAT-10, MBSImP ratings, clinician ratings of oral intake using the FOIS (Crary et al., 2005), and measures of airway safety during swallowing via the Penetration-Aspiration Scale (PAS) (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996) were analyzed.
Chapter 2: Literature Review

Swallowing is comprised of a series of complex neuromuscular events using skeletal and smooth muscles. The act of swallowing involves upward of fifty muscles and six cranial nerves, and it can be broken down into four stages (Logemann, 1998). Swallowing is regulated by a complex interaction of afferent (sensory) and efferent (motor) neurons; and, there are both cortical and subcortical components to swallowing. Bilateral hemispheric motor and premotor cortical areas are involved in the initiation of a swallow. Subcortical involvement in swallowing is controlled by the central pattern generator, located in the medulla oblongata, which is comprised of a collection of brainstem nuclei. The nucleus tractus solitarius (comprised of cranial nerves VII, IX, and X) and the nucleus ambiguus (comprised of cranial nerves IX, X, and XI) are the two main groups of interneurons within the central pattern generator (Logemann, 1998).

Normal Swallowing

A normal swallow can be broken down into sequential steps and is generally described in four phases: oral preparatory, oral, pharyngeal and esophageal phase (Logemann, 1998). The phases of swallowing are outlined below:

*Oral Preparation Phase*

The oral preparation stage is the first stage of swallowing and begins by introducing a food substance, a bolus, to the oral cavity. For solid food this may include the lips closing
around the item and the teeth closing on the bolus to fracture it. The oral tongue accepts the bolus and moves it posteriorly and laterally to the teeth for mastication. The lips are the initial valve that close, creating a chamber in the oral cavity, to prevent material from escaping anteriorly. The bolus is then prepared for swallowing via a rotary chewing motion of the mandible while mixing with saliva produced by the parotid and submandibular glands (Logemann, 1998). During mastication of a solid bolus, sensory feedback coordinates the tongue position and shape to the moving mandible in order to keep the bolus in contact with the teeth as well as to determine the need for additional mastication. Once the oral tongue perceives the bolus viscosity has reached the appropriate texture for swallowing, the bolus is medialized to the dorsum of the tongue to begin the oral (transit) stage of the swallow.

**Oral Phase**

Moving the bolus from the tongue to the pharynx comprises the oral stage of the swallow. The pressure required to propel the bolus posteriorly through the oral cavity begins when the lips are held closed and the tongue tip is placed against the teeth or gums. Almost simultaneously, the posterior tongue depresses as the remaining anterior and medial portions of the tongue elevate and press against the hard palate. As the positive pressure builds up in the anterior oral cavity, the bolus is propelled posteriorly into the pharynx. The required lingual pressure to propel the bolus increases with bolus viscosity (Logemann, 1998).

**Pharyngeal Phase**

The pharyngeal swallow is triggered as the bolus moves from the oral cavity to the pharynx, typically at the point where the head of the bolus reaches the faucial arches
As the bolus reaches this point, the velopharyngeal port closes, creating a valve to force the bolus down into the pharynx and preventing it from entering the nasal cavity. Upon velopharyngeal port closure, the hyolaryngeal complex begins to rise and the laryngeal vestibule begins to close at three levels. Respiration is suspended at this point during the swallow. The three levels of laryngeal vestibule closure include adduction of the true vocal folds, tilting of the arytenoid cartilages anteriorly to approximate the false folds resulting in closure, and retroversion of the epiglottis to close over the arytenoid cartilages, effectively preventing material from entering the laryngeal vestibule. The retroversion of the epiglottis occurs as the hyolaryngeal complex elevates and the tongue base retracts to contact the posterior pharyngeal wall. As this three-layered valve is closing, the bolus is divided at the level of the vallecula, resulting in flow down either side of the pharynx through the lateral channels. The elevation of the hyolaryngeal complex coincides with relaxation of the cricopharyngeal muscle, which functions to open the upper esophageal sphincter (pharyngoesophageal segment). The pressure generated on the bolus from the valves at the nasopharyngeal port, laryngeal vestibule closure, and contact of the tongue base and posterior pharyngeal wall, drives the bolus to enter the esophagus (Kim, 2005; Logemann, 2007).

**Esophageal Phase**

The esophageal phase begins as the bolus enters the esophagus and continues until the bolus passes through the lower esophageal sphincter. It consists of upper esophageal sphincter contraction, esophageal propulsion, and relaxation of the lower esophageal sphincter (Lang, 2009).
The oral preparatory and much of the oral phase are under voluntary control. Involuntary control takes over when the initiation of the pharyngeal swallow occurs late in the oral phase. The pharyngeal and esophageal phases of swallowing are under involuntary control. This knowledge is important when determining appropriate treatment strategies depending on the etiology of the swallowing problem. Due to the rapid transition between the oral and pharyngeal phase when the swallow reflex is triggered, clinicians often refer to the act of swallowing as the oropharyngeal swallow.

**Dysphagia**

The complexity of swallowing is often taken for granted until difficulty arises. Dysphagia is the medical term for difficulty swallowing and involves difficulty moving food or saliva from the mouth to the stomach (Logemann, 1998). Dysphagia severity can range from difficulty eating certain food types and textures to complete inability to swallow and can occur at all ages and across all populations. Dysphagia may be iatrogenic, psychogenic, or the result of congenital abnormalities, structural damage, infectious disease, and/or other medical or neurological processes (Logemann, 2007; Palmer et al., 2000). These conditions may include: cancer of the head and neck, brain, or esophagus; a neurological condition affecting the nervous system, including stroke, traumatic brain injury, dementia, Parkinson’s disease, ALS, and MS; an esophageal disorder including GERD and dysmotility; deconditioning; psychogenic processes; and pharmacology.

Research has demonstrated that dysphagia is surprisingly common in the general population, although the exact incidence and prevalence is not well established (Eslick &
There are several adverse health conditions that can negatively impact swallowing function. As disease risk increases with the natural ageing process, the risks of developing swallowing-related issues simultaneously increase.

Assessment of Dysphagia

Dysphagia is a medical condition, therefore must be diagnosed by a physician. This diagnosis is often based on patient report and/or on the assessments performed by a speech-language pathologist (SLP). Individuals and/or their caregivers may notice signs or symptoms associated with dysphagia that precipitate an assessment, thus leading to a diagnosis. Signs and symptoms of dysphagia may include: coughing or choking, pain with swallowing (odynophagia), drooling, wet vocal quality or hoarseness, regurgitation, decreased intake or refusal to eat, sensation of food getting stuck in the throat or chest, and unexpected weight loss.

Assessment of dysphagia includes patient report, a thorough medical history review to determine possible etiologic factors, an oral motor examination, and an evaluation. A clinical or instrumental evaluation may be performed to assess for dysphagia.

Clinical Swallowing Assessment

A clinical swallowing evaluation involves assessing secretion management and, if appropriate, the tolerance of food and liquid consistencies. Boluses of ice chips or water are often administered first to determine aspiration risk. Observations of bolus control, laryngeal elevation, and the presence or absence of a reflexive cough, are most commonly assessed. If symptoms are severe (i.e. choking, gagging), termination of the clinical evaluation and a
recommendation for an instrumental assessment may be warranted. If no overt signs or symptoms of dysphagia exist, continuation of the assessment using various food consistencies and volumes may be appropriate to determine the least restrictive oral diet for the individual.

*Modified Barium Swallow (MBS)*

A commonly-used instrumental assessment of swallowing is the MBS (Logemann, 1998). The MBS is a dynamic assessment performed to identify oral, pharyngeal and/or esophageal dysphagia, as well as to examine an individual’s response to treatment strategies. This test is performed under the direction of a SLP in conjunction with a radiologist. The patient is seated in the upright position, if able, to mimic optimal positioning for safe eating. Various bolus sizes and viscosities of barium contrast are administered as appropriate. Protocols may differ by facility but typically include thin liquid, nectar thick liquid, pudding, and a solid consistency. Some facilities follow a standardized protocol for bolus administration and study interpretation, the Modified Barium Swallow Impairment Profile (MBSImP) (Martin-Harris et al., 2008).

The MBSImP is a research-based, standardization of the MBS. The MBSImP assesses the integrity of 17 critical components of swallowing broken down into the oral, pharyngeal, and esophageal phases (Martin-Harris et al., 2008). Comprised within the MBSImP is a specific tool to assess airway safety known as the Penetration-Aspiration Scale (PAS) (Rosenbek et al., 1996).
Regardless of protocol, the MBS allows for visualization of the motor response and structural movements in relation to bolus flow, volume, and texture. Oral, pharyngeal, and esophageal components of the swallow mechanism are viewed under fluoroscopy. Close attention is paid to the physiological components of the swallow, as well as the presence of laryngeal penetration and aspiration. Treatment strategies are implemented as warranted with the ultimate goal of achieving an efficient swallow and airway safety.

The MBS is a relatively safe examination. However, contraindications do exist. Contraindications to conducting a MBS on a patient include: poor mental status, patient’s goals and wishes, particularly at the end stage of life, allergy to barium contrast, and radiation dosage. Additional limitations to this type of assessment include: cost, radiation exposure, patient positioning, and availability of a fluoroscopy suite.

**Risk of Radiation Exposure**

The MBS utilizes fluoroscopy as the imaging modality to identify the presence, severity, and pattern of dysphagia. Patient radiation dose from a MBS is relatively low, between 0.2 and 0.85 mSv (Bonilha et al., 2013; Chan, Chan, & Lam, 2002; Chau & Kung, 2009; Hayes et al., 2009; McLean, Smart, Collins, & Varas, 2006; Moro & Cazzani, 2006; Weir et al., 2007; Wright, Boyd, & Workman, 1998). The most important factor influencing patient doses during MBS is the total radiation exposure time. Eleven peer-reviewed manuscripts have reported fluoroscopy times or fluoroscopy time guidelines for MBSs (Chan et al., 2002; Chau & Kung, 2009; Crawley, Savage, & Oakley, 2004; Hayes et al., 2009; B. Martin-Harris & Jones, 2008; McLean et al., 2006; Moro & Cazzani, 2006; Weir et al., 2007;
Wright et al., 1998; Zammit-Maempel, Chapple, & Leslie, 2007). Review of this literature reveals a wide range of radiation exposure times during MBSs (2.5 – 18 minutes). These studies show that factors affecting radiation exposure time in MBSs include: medical diagnosis, swallowing impairment severity, clinician experience, and use of a standardized protocol (Bonilha et al., 2013). The average radiation exposure time using MBSImP has been reported to be 2.9 min with a 95% confidence interval of 2.8 to 3.0 min (range = 0.4 to 8.0 min). This is well within the range of exposure times reported as acceptable in the literature (Bonilha et al., 2013).

Risk of Aspiration

Aspiration is a common risk when undergoing a MBS and often occurs with dysphagic patients, whether or not fluoroscopy is being performed to visualize it. Aspiration is defined as secretions, food, or liquids entering into the trachea below the level of the true vocal folds (Logemann, 1998). Aspiration may result in a reflexive cough response, which is often uncomfortable to an individual. However, as many as 25-30% of individuals who undergo a MSB demonstrate silent aspiration (Ramsey, Smithard, & Kalra, 2005). Silent aspiration is defined as aspiration without an outward sign of swallowing difficulty (no coughing, no throat clearing, no sign of distress) (Ramsey et al., 2005). Regardless of type, aspiration can be clearly observed during videofluoroscopy. One of the main indications to perform a MBS is to trial compensatory or therapeutic strategies in order to improve airway safety by reducing or eliminating aspiration from occurring.
Therapeutic techniques are either compensatory or restorative in nature. Compensatory strategies involve adjustments used to compensate for a problem and facilitate safe swallowing. These strategies may include postural changes or alterations to bolus delivery, size, texture, temperature, and/or rate of delivery. Postural changes during swallowing may be effective in redirecting bolus flow. For example, in the case of unilateral vocal fold paralysis, instructing an individual to turn his or her head to the affected side will redirect the bolus to flow down the stronger lateral channel, thus resulting in a safer, more efficient swallow. Proper interpretation of the physiologic impairments of the swallow is imperative in order to implement appropriate compensatory strategies. Therapeutic or rehabilitative intervention may involve altering the swallow response by varying the musculature and/or timing of the swallow. Rehabilitative exercises, unlike compensatory strategies, have an end goal of making improvements that generalize to a functional swallow. For example, an effortful swallow may be implemented if pharyngeal residue as a result of impaired pharyngeal contraction is observed.

Head and Neck Cancer (HNC)

*Incidence and Prevalence of HNC*

There has been a significant rise in the incidence of HNC over the past decade. Although the use of tobacco and alcohol resulting in mucosal transformations to malignancy have decreased, the rates of oropharyngeal cancer have significantly increased as a direct result of a virally mediated cancer associated with the human papillomavirus (HPV) (Deschler, Richmon, Khariwala, Ferris, & Wang, 2014). HPV-related squamous cell
carcinoma of the oropharynx has increased 225% from 1988 to 2004 (Deschler et al., 2014). This epidemiologic shift is impacting individuals (males > females) in their forties and fifties who have no significant history of tobacco or alcohol use (Deschler et al., 2014).

Two oncogenic high-risk HPV types, HPV 16 and HPV 18, are attributed to more than 90 percent of HPV-related or HPV-positive (HPV+) oropharyngeal cancers (Cleveland et al., 2011). The specific subtype HPV 16 has been associated with 85-90% of all HPV-related oropharyngeal cancers (Chaturvedi, Engels, Anderson, & Gillison, 2008; Cleveland et al., 2011; Kreimer, Clifford, Boyle, & Franceschi, 2005). Persistent HPV infection in the oral cavity can lead to altered immune function and genetic damage, which may yield progression to squamous cell carcinoma specifically within the tonsil and base of tongue regions (Marur, D'Souza, Westra, & Forastiere, 2010).

Research has shown significant differences, including improved therapeutic response and overall survival with oropharyngeal cancer, when HPV infection is present (HPV+) compared to when the virus is absent (HPV-) (Chaturvedi et al., 2008; Fakhry et al., 2008). An ongoing clinical trial is underway, investigating whether a less intense treatment will have the same therapeutic effect on individuals with HPV+ tumors. To date, it remains unknown if there are differences in functional outcomes, including swallow physiology, between these heterogeneous groups (HPV+ and HPV-).

Incidence of Dysphagia in HNC

The incidence of dysphagia within the HNC population is high, with symptoms continuing to progress for several years post treatment (Lazarus, 1993; Smith et al., 2000). It
is reported that as many as 50% of HNC patients are left with permanent swallowing deficits following cancer treatment (Nguyen et al., 2002). However, it has been suggested that the reported incidence is underestimated due to discrepancies between patient report and objective findings of swallow pathophysiology on instrumental assessment (Kendall et al., 2014; Lazarus, 1993).

Dysphagia has been reported to be as high as 40% at initial cancer diagnosis (Stenson et al., 2000) and it often remains the primary residual side effect of treatment after the tumor is eradicated (Murphy & Gilbert, 2009). Dysphagia is often the most problematic short-term and long-term effect seen in the HNC population. Long-term dysphagia can result in critical consequences, including aspiration and dietary inadequacies, leading to malnutrition and its associated adverse effects (Murphy & Gilbert, 2009).

**Impact of Cancer Treatment Modalities on Swallowing Function**

The treatment modalities for HNC, which include surgery, radiation and/or chemoradiation, often result in dysphagia or exacerbate an existing dysphagia. These treatment modalities have adverse effects on physiologic function as well as quality of life. Studies have shown that dysphagia is often present pretreatment with severity correlating with disease stage (Pauloski et al., 2000; Starmer, Gourin, Lua, & Burkhead, 2011; van der Molen et al., 2009). Regardless of treatment modality, tumors of the larynx and hypopharynx have been shown to cause worse swallow function than those in the oral cavity and oropharynx (Stenson et al., 2000). This is due to the impact the tumor has on the critical pharyngeal phase of swallowing.
Non-surgical Treatment for HNC

Treatment of HNC has shifted over the past decades to focus on “organ sparing” therapies, specifically radiation therapy with or without chemotherapy. The most commonly used type of radiation for this population is Intensity-Modulated Radiation Therapy (IMRT) (Lee, Puri, Blanco, & Chao, 2007). Dose modulation allows for increased radiation doses to be delivered to specific areas of tumor involvement while providing reduced radiation exposure to sensitive areas of surrounding normal tissue (Lee et al., 2007). Although these techniques have been proven to be effective, without a decrease in overall survival, they do produce both acute and long-term adverse effects that impact swallowing safety and quality of life (Lazarus et al., 2007; Murphy & Gilbert, 2009). Acute side effects of radiation therapy include: radiation dermatitis, pain, loss of energy, tooth decay, mucositis, soft tissue edema, weight loss, xerostomia, impaired taste, voice changes, muscle fibrosis, trismus, and dysphagia (Murphy & Gilbert, 2009). The most common and problematic long-term side effects of radiation therapy include xerostomia, muscle fibrosis, trismus and dysphagia. Due to the sequelae of long-term dysphagia, including reduced quality of life, malnutrition, aspiration, and death, early identification of a swallowing impairment and intervention is critical.

Characteristics of dysphagia secondary to radiation therapy are dependent primarily upon tumor size and the presence or absence of metastatic neck disease. These oncologic features greatly impact the radiation field and dose required for definitive treatment. Impaired base of tongue retraction and reduced hyolaryngeal elevation have been identified
as two of the most salient features of dysphagia following radiation therapy for HNC (Logemann et al., 2008). Lingual strength in oral and oropharyngeal cancer patients treated with primary CRT has been found to be lower than in that seen in control healthy individuals (Lazarus et al., 2007; Lazarus et al., 2000). Lingual strength has also been found to correlate with impaired airway protection resulting in aspiration (Butler et al., 2011).

Oncology providers are increasingly recognizing the importance of early identification of swallowing impairment or even prophylactic swallowing therapy to prevent or minimize adverse effects of cancer treatments. This concept is supported in the literature, including two randomized control trials, which have demonstrated that early dysphagia therapy and management is a means of maintaining oropharyngeal function (Carnaby-Mann, Crary, Schmalfuss, & Amdur, 2012; Carroll et al., 2008; Kotz et al., 2012; Kulbersh et al., 2006; van der Molen et al., 2011).

**Surgical Treatment for HNC**

Surgery for HNC may alter an individual’s cosmetic appearance, his/her quality of life, and his/her functionality, including the ability to talk, smell, chew, and/or swallow (Biazevic et al., 2010; Dwivedi et al., 2012; Furia, 2001; Pauloski et al., 1993; Yang, Chen, Huang, Pan, & Li, 2010). Post-operative swelling may occur but often resolves within a few weeks. In general, surgical changes are often predictable based on the location and stage of the primary tumor stage of the disease (Colangelo, Logemann, Pauloski, Pelzer, & Rademaker, 1996). For example, a partial glossectomy procedure can greatly impact swallow functioning. Lingual strength and mobility have been correlated with dietary intake.
and aspiration (Butler et al., 2011; Lazarus et al., 2000). However, the pharyngeal phase of the swallow is not typically impacted when resection is limited to the anterior tongue and oral cavity (Pauloski et al., 1993). Reconstruction of the lingual deficit following glossectomy may contribute to the consequential dysphagia in the initial postoperative phase. However, multiple articles have reported a return to baseline status by one year (Brown, 2010; O’Connell, 2008). The functional deficits that result from surgical intervention are limited to specific anatomic and related neurophysiologic changes caused by the surgery itself (Kronenberger & Meyers, 1994). As in the example of a partial glossectomy patient, one would predict functional deficits to include impaired speech intelligibility and oral phase dysphagia. Potential oral phase impairments include: difficulty with bolus control and impaired sensation resulting in pooling on the surgical side, impaired bolus preparation/formation, impaired anterior-posterior transport of the bolus, impaired lingual driving force and propulsion into the pharynx. These impairments are treated by compensatory strategies to overcome impaired sensation and reduced strength including: head tilt to the stronger side, and direct food placement on native tongue. Rehabilitative exercises are often warranted to improve lingual range of motion and strength (Llewellyn, McGurk, & Weinman, 2006; Newell, Ziegler, Stafford, & Lewin, 2004).

As outlined above, one of the most important differences between functional outcomes and treatment modality is that an individual’s swallow function typically improves after surgery, while it tends to worsen after radiation therapy due to the adverse effects of treatment (Pauloski et al., 1994; Pauloski, Rademaker, Logemann, & Colangelo, 1998).
However, often a combined modality to treat the cancer (surgery plus radiation or chemoradiation) is required for curative intent. Combined therapies often have a larger impact on swallowing function in both the acute and long-term phases of recovery than single therapies alone. In general, HNC patients often report that their swallowing is superior to actual performance observed during fluoroscopy or endoscopy (Kendall et al., 2014; Lazarus, 1993). This discrepancy may be related to how history intake is conducted and the high incidence of silent aspiration within this population.

Silent aspiration, a direct result of impaired airway protection, has been reported to be as high as 18.5% at the time of HNC diagnosis, and ranges from 22-60% following specific cancer treatment (Denaro, Merlano, & Russi, 2013). In addition, it has been shown that less than half of dysphagic patients report their dysphagia symptoms to health care professionals unless they are directly asked about their swallowing-related difficulties (Cichero & Clave, 2012; Ekberg, Hamdy, Woisard, Wuttge-Hannig, & Ortega, 2002). However, as stated above, patient report remains an essential aspect of the diagnosis of dysphagia.

Pauloski et al., (2002) and Rogus-Pulia et al., (2014) have confirmed that individuals with HNC can decipher changes in their swallowing function, but a subjective, patient-reported or clinician-reported outcome tool that correlates with clinician findings of swallowing pathophysiology has not yet been identified. Therefore, identifying a useful and reliable way to predict pathophysiology and, airway safety impairments, and to utilize it as a means to monitor progression of dysphagia, is essential for this patient population.
Subjective outcome measures can be easy to administer but are only useful for these stated purposes if they correlate with measures of swallowing physiology.

The purpose of the current study was to determine the relationships between patient self-ratings of swallowing function using the EAT-10, clinician ratings of oral intake using the FOIS, physiologic measures of swallowing using the MBSImP, and airway safety during swallowing via the PAS in individuals with HNC.

Research Hypotheses

Specific Aim 1: Assess the relationship between patient- and clinician-ratings of swallowing function in individuals with HNC.

Hypothesis 1: Patient self-ratings of swallowing function using the EAT-10 will moderately correlate with clinician rated measures of swallow pathophysiology using the MBSImP.

Two studies have examined the relationship between patient- and clinician-ratings of swallowing function in individuals with HNC and have found no significant correlations (Kendall et al., 2014; Rogus-Pulia et al., 2014). The current study assessed the same relationship using a validated, patient-completed, screening tool, the EAT-10, and a standardized MBS scoring protocol, the MBSImP. A moderate correlation was anticipated as a result of clinical experience and use of these outcome measures by the primary investigator. Strong correlations were not anticipated due to the targeted convenience sample, any individual with a history of HNC regardless of tumor site and treatment modality, and the previous literature stated above (Kendall et al., 2014; Rogus-Pulia et al., 2014), along with the high incidence of silent aspiration for this population (Denaro et al., 2013).
Specific Aim 2: Assess the relationship between patient-rated swallowing function and clinician-rated airway safety in individuals with HNC.

Hypothesis 2: Patient self-ratings of swallowing function using the EAT-10 will moderately correlate with clinician rated measures of airway safety (PAS scores).

Individuals with HNC often present with reduced lingual strength, as a result of cancer treatment, compared to that seen in healthy controls (Lazarus et al., 2007; Lazarus et al., 2000). Lingual strength has been found to correlate with impaired airway protection resulting in aspiration (Butler et al., 2011). Therefore, it was hypothesized that the EAT-10 would not only moderately correlate with clinician-rated measures of pathophysiology of swallowing function, but would also correlate with clinician-rated measures of airway protection/airway safety using the PAS. Strong correlations were again not anticipated due to the targeted convenience sample, the previous literature evidencing no relationship between patient perception and clinician finding of dysphagia (Kendall et al., 2014; Rogus-Pulia et al., 2014), and the high incidence of silent aspiration for this population (Denaro et al., 2013).

Specific Aim 3: Assess the relationship between patient-rated swallow function and clinician-rated functional oral intake in individuals with HNC.

Hypothesis 3: Patient self-ratings of swallowing function using the EAT-10 will moderately correlate with clinician-rated measures of functional oral intake using the FOIS.

As stated above, it was hypothesized that the EAT-10 would correlate with pathophysiological findings resulting in dysphagia. Reduced lingual strength is a common
physiological impairment seen in patients with HNC as a result of cancer treatment (Lazarus et al., 2007; Lazarus et al., 2000). Lingual strength and mobility have been previously correlated with dietary intake and aspiration (Butler et al., 2011; Lazarus et al., 2000). Therefore, it was hypothesized that the EAT-10 would correlate with clinician-rated measures of functional oral intake using the FOIS. Strong correlations were again not anticipated due to the targeted convenience sample and due to the FOIS being validated for use with the individuals with a history of stroke (Crary et al., 2005), not HNC.
Chapter 3: Methods

Participants

The Ohio State University Cancer Institutional Review Board and the Clinical Scientific Review Committee for the James Comprehensive Cancer Center approved this study. All research participants signed an approved consent form prior to participation in this study. See Appendix E for a copy of the consent form.

Forty-five individuals (34 males and 10 females) ranging in age from 32 to 92 years (M = 64.68; SD = 11.84) referred to The Ohio State, James Comprehensive Cancer Center, Head and Neck Oncology, Speech Pathology clinic for a MBS study between September 2014 and January 2015 were screened for potential inclusion in this study. Inclusion criteria included: 1) referral for a MBS study due to reported or suspected dysphagia, 2) confirmed diagnosis of a HNC, and 3) participant report of literacy. Exclusion criteria included: 1) if the research assistant completing the MBS informally deemed the participant unable to follow multi-step commands based on history intake and completion of an oral motor exam and 2) the patient reported to be illiterate when directly asked by the research assistant, “Can you read?” One participant was excluded due to reporting he was unable to read, therefore unable to independently complete the EAT-10. The remaining forty-four patients from this convenience sample were recruited and consented at the time of their MBS by the primary
investigator or a research team member. All participants were assigned to the same task, completion of a patient survey.

Materials

_Eating Assessment Tool – 10 (EAT-10)_

The EAT-10 (Belafsky et al., 2008) is a symptom-specific, swallowing screening, outcome instrument designed for patients to rate the degree of self-perceived swallowing impairments. It is reported to be a validated and reliable instrument to document dysphagia severity and monitor response to medical treatment for swallowing disorders by individuals with swallowing impairment (Belafsky et al., 2008). It is currently unknown how self-reports of swallowing function using the EAT-10 are associated with objective measures of swallow physiology, airway safety, or functional oral intake for individuals with HNC.

The EAT-10 (Belafsky et al., 2008) is comprised of 10 questions (Appendix A). Each question is rated using a 0-4 ordinal scale in which 0 indicates no impairment and 4 indicates severe problem. An overall score is calculated as the sum of the 10 questions, providing a score with a range from 0-40 for which higher scores indicate greater perceived impairment.

_Functional Oral Intake Scale (FOIS)_

The FOIS (Crary et al., 2005) is a validated 7-point ordinal scale indexing the amount and type of oral intake (food) an individual is able to consume (Appendix B). It is completed and scored by a health care provider. Levels 1-3 are the most severe, indicating an individual is “tube-dependent” and levels 4-7 indicate total oral intake to maintain nutrition and
hydration.

Modified Barium Impairment Profile (MBSImP)

The MBSImP (Martin-Harris et al., 2008), is a research-based, standardization of the MBS (Appendix C). The MBSImP assesses the integrity of 17 critical components of swallowing broken down into the oral, pharyngeal and esophageal phases.

The oral and pharyngeal phase components were rated and summed for this study. Each component is rated using a 3- to 5-point ordinal scale. The oral phase components include: lip closure, tongue control during bolus hold, bolus preparation/mastication, bolus transport/lingual motion, oral residue, initiation of pharyngeal swallow. The sum of the six oral phase components ranges from 0-22; 0 indicates no impairment and 22 indicates a severe impairment. The pharyngeal phase components include: soft palate elevation, laryngeal elevation, anterior hyoid excursion, epiglottic movement, laryngeal vestibule closure, pharyngeal stripping wave, pharyngeal contraction, pharyngoesophageal segment opening, tongue base retraction, and pharyngeal residue. The sum on the 10 pharyngeal phase components ranges from 0-29; 0 indicates no impairment and 29 indicates a severe impairment. The sum of the combined oral and pharyngeal phases ranges from 0-51.

Penetration-Aspiration Scale (PAS)

The PAS (Rosenbek et al., 1996) is a validated, ordinal, 8-point scale used to assess airway protection (Appendix D). The PAS score is based on the depth of bolus entry into the airway and the subsequent patient response. The PAS can be broken down into three groups designating complete airway protection (level 1), laryngeal penetration (levels 2-5) and
aspiration (levels 6-8).

Procedures

Following enrollment into the study, participants independently completed the EAT-10. The FOIS was completed by an SLP/research team member, based on the participant’s verbal report of their current oral intake, prior to the MBS. An SLP/research team member then completed a standardized MBS in conjunction with a radiologist or radiation technician. Participants were seated upright in a Hausted videofluoroscopy imaging chair. All MBSs were conducted within less than 5 minutes of fluoroscopy time. Varibar Barium® products were administered while lateral and anterior-posterior projections of fluoroscopy were captured at thirty frames per second. Varibar Barium® products were used to control for the viscosity of the contrast. The typical administration of barium contrast included thin liquid (one teaspoon, single cup sip, sequential swallows via cup), nectar thick liquid (single cup sip), pudding consistency (two teaspoons) and one half of a cracker coated with pudding barium contrast. Specific viscosities and trials were eliminated if deemed unsafe for the individual participant based on clinical judgment of the SLP/research team member. Two independent members of the research team then rated each MBS using the MBSImP to achieve an oral phase impairment score, a pharyngeal phase impairment score, a combined oral and pharyngeal impairment score, and a PAS score. The raters then conferred until absolute agreement for each measure was obtained. These agreed upon measures were utilized for analysis.
**Analysis**

Descriptive statistics were utilized to describe patient demographics in this cohort. In addition, the statistical analyses associated with each of the Specific Aims are presented below. All statistical analyses were performed using SPSS 22.0 (IBM Corp., Armonk, NY).

Specific Aim 1: To assess the relationship between patient- and clinician-ratings of swallowing function in individuals with HNC, a Pearson’s correlation coefficient was calculated between the total EAT-10 overall score and the MBSImP pharyngeal impairment score with alpha set at 0.05.

Specific Aim 2: To assess the relationship between patient-rated swallowing function and airway safety in individuals with HNC, a nonparametric Spearman’s correlation coefficient was calculated between the PAS total score and the EAT-10 total score with alpha set at 0.05.

Specific Aim 3: To assess the relationship between patient-rated swallow function and clinician-rated functional oral intake in individuals with HNC, a nonparametric, Spearman’s correlation coefficient was calculated between the FOIS and the EAT-10 and tested to determine whether it was significantly different than zero with an alpha level set at .05.

Correlation strengths were defined as: 0.0 = zero, less than 0.1 = weak, 0.1 – 0.3 = modest, 0.3 - 0.5 = moderate, 0.5 – 0.8 = strong, 0.8 – 0.9 = very strong, and 1 = perfect (Dancey & Reidy, 2004).
Additional Analysis

To assess any potential differences in patient-reported swallowing impairment levels in “safe” vs. “unsafe” swallowers, patients were divided into two safety groups. Participants with safe swallowing included those with a PAS ≤ 2 and those with unsafe swallowing had a PAS of ≥ 3. A t-test was conducted to compare the mean EAT-10 scores of the safe and unsafe swallowers.

Reliability

Inter- and intra-rater reliability was analyzed using the intraclass correlation coefficient (ICC). Inter-rater reliability was calculated from all MBSImP ratings obtained from three SLPs compared to the primary investigator. Intra-rater reliability for all data collected was calculated from measures made by the primary investigator only. All 16 components of the oral and pharyngeal phases of swallowing and PAS scores were included for reliability analysis.
Chapter 4: Results

The study sample consisted of 44 individuals, thirty-four males and ten females, with an age range of 32 – 92 years (mean age = 64.7 years), diagnosed with HNC. Tumor location included: oropharynx (47.7%), larynx (15.9%), oral cavity (9.1%), pharynx (6.8%), maxillary sinus (4.5%), thyroid (2.3%), nasopharynx (2.3%), and combined sites (11.4%). Treatment modalities included: no treatment (11%), radiation therapy (2%), chemoradiation (32%), and surgery plus adjuvant therapy (55%). Age, gender, tumor site, treatment modality and HPV status are shown in Table 1.

<table>
<thead>
<tr>
<th>Age</th>
<th>Tumor Site</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>Oral Cavity</td>
<td>4</td>
<td>9.1%</td>
</tr>
<tr>
<td>Range</td>
<td>Maxillary Sinus</td>
<td>2</td>
<td>4.5%</td>
</tr>
<tr>
<td></td>
<td>Nasopharynx</td>
<td>1</td>
<td>2.3%</td>
</tr>
<tr>
<td>Gender</td>
<td>Oropharynx</td>
<td>21</td>
<td>47.7%</td>
</tr>
<tr>
<td>Male</td>
<td>Pharynx</td>
<td>3</td>
<td>6.8%</td>
</tr>
<tr>
<td>Female</td>
<td>Larynx</td>
<td>7</td>
<td>15.9%</td>
</tr>
<tr>
<td></td>
<td>Thyroid</td>
<td>1</td>
<td>2.3%</td>
</tr>
<tr>
<td>Treatment Modality</td>
<td>Combined sites</td>
<td>5</td>
<td>11.4%</td>
</tr>
<tr>
<td>No Treatment</td>
<td>Radiation Alone</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Chemoradiation</td>
<td>14</td>
<td>32%</td>
</tr>
<tr>
<td></td>
<td>Combined modality</td>
<td>24</td>
<td>55%</td>
</tr>
</tbody>
</table>

**HPV Status (Oropharynx tumors)**

<table>
<thead>
<tr>
<th></th>
<th>HPV+</th>
<th>13/21 (61.9%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined modality</td>
<td>HPV -</td>
<td>4/21 (19.0%)</td>
</tr>
<tr>
<td>(surgery + radiation</td>
<td>HPV status</td>
<td>4/21 (19.0%)</td>
</tr>
<tr>
<td>or surgery +</td>
<td>Unknown</td>
<td></td>
</tr>
<tr>
<td>chemoradiation)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1 Descriptive Statistics for study participants (n = 44).
**EAT-10 and MBSImP**

The relationship between the EAT-10 and the MBSImP was investigated using Pearson’s correlation coefficient. Eight of the seven hundred and four ratings of swallow physiology were imputed due to missing data for six of the 44 participants. These ratings consisted of six in the oral phase and two in the pharyngeal phase (components 3 and 13). Maximum severity ratings for each data point for each of those components were chosen based on the pathophysiology of the swallow. Specifically, when data for component 3, bolus preparation/mastication, were missing, it was due to the SLP research team member deeming solid consistency as unsafe for the participant at the time of the MBS. Therefore, the highest severity rating (3) was chosen for analysis. The two instances of missing data for component 13, pharyngeal contraction, were due to identification of an esophageal stricture or complete stenosis impeding bolus flow. Therefore, it is logical to assume the highest severity rating, bilateral bulging (3), would occur if there were a stricture distal to the pharynx.

As shown in Figure 1, the relationship between the EAT-10 and the combined MBSImP oral and pharyngeal impairment scores revealed a moderate positive correlation ($r = .459; p = 0.002$). Sensitivity analysis using the minimum score for each imputed rating revealed a negligible effect on the outcome for the relationship between the EAT-10 and the combined oral and pharyngeal swallowing impairment scores, ($r = .481; p = 0.001$). As shown in Figure 2, strong positive correlations ($r = .515; p < 0.001$) were observed between the pharyngeal impairment scores and the EAT-10. Sensitivity analysis using the minimum
score for each imputed rating was again conducted and revealed a negligible effect on the outcome for the relationship between the EAT-10 and the pharyngeal impairment alone ($r = .511; p < 0.001$). As shown in Figure 3, the relationship between the EAT-10 and the oral phase impairment was not significant ($r = .265; p = .082$).

Figure 1: Correlation between the EAT-10 and the combined MBSImP oral and pharyngeal impairment scores.
Figure 2: Correlation between the EAT-10 and the pharyngeal impairment scores.

Figure 3: Correlation between the EAT-10 and the oral impairment scores.
Correlations between each question on the EAT-10 and the combined oral and pharyngeal MBSImP score were calculated to determine which specific patient reported measures were related to the physiological findings. As shown in Table 3, listed in order of significance, six of the ten questions showed moderate positive correlations ($p < .05$) with overall swallowing impairment scores. In addition, the relationship between each of the oral and pharyngeal phase components on the MBSImP and each question on the EAT-10 was analyzed. As shown in Table 4, listed in order of significance, eight of the 16 components showed moderate positive correlations ($p < .05$) with EAT-10 ratings.

<table>
<thead>
<tr>
<th>Question Number</th>
<th>EAT-10 Question</th>
<th>Correlation between EAT-10 and the Combined Oral and Pharyngeal MBSImP scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Swallowing is stressful.</td>
<td>$r = .444, p = .003^{**}$</td>
</tr>
<tr>
<td>2</td>
<td>My swallowing problem interferes with my ability to go out for meals.</td>
<td>$r = .427, p = .004^{**}$</td>
</tr>
<tr>
<td>4</td>
<td>Swallowing solids takes extra effort.</td>
<td>$r = .414, p = .005^{**}$</td>
</tr>
<tr>
<td>3</td>
<td>Swallowing liquids takes extra effort.</td>
<td>$r = .349, p = .020^*$</td>
</tr>
<tr>
<td>1</td>
<td>My swallowing problem has caused me to lose weight.</td>
<td>$r = .346, p = .021^*$</td>
</tr>
<tr>
<td>9</td>
<td>I cough when I eat.</td>
<td>$r = .301, p = .047^*$</td>
</tr>
<tr>
<td>5</td>
<td>Swallowing pills takes extra effort.</td>
<td>$r = .280, p = .066$</td>
</tr>
<tr>
<td>7</td>
<td>The pleasure of eating is affected by my swallowing.</td>
<td>$r = .252, p = .099$</td>
</tr>
<tr>
<td>6</td>
<td>Swallowing is painful.</td>
<td>$r = .071, p = .645$</td>
</tr>
<tr>
<td>8</td>
<td>When I swallow food sticks in my throat.</td>
<td>$r = .052, p = .739$</td>
</tr>
</tbody>
</table>

Table 2 Correlations between the EAT-10 and MBSImP scores.

** The double asterisk denotes statistical significance at the 0.01 level.
* The single asterisk denotes statistical significance at the 0.05 level.
<table>
<thead>
<tr>
<th>MBSImP component</th>
<th>EAT-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>C8 – Laryngeal Elevation</td>
<td>$r = .486, p = .001^{**}$</td>
</tr>
<tr>
<td>C15 – Tongue Base Retraction</td>
<td>$r = .439, p = .003^{**}$</td>
</tr>
<tr>
<td>C9 – Anterior Hyoid Excursion</td>
<td>$r = .427, p = .004^{**}$</td>
</tr>
<tr>
<td>C11 – Laryngeal Vestibular Closure</td>
<td>$r = .416, p = .005^{**}$</td>
</tr>
<tr>
<td>C12 – Pharyngeal Stripping Wave</td>
<td>$r = .396, p = .008^{**}$</td>
</tr>
<tr>
<td>C3 – Bolus Preparation/Mastication</td>
<td>$r = .378, p = .011^*$</td>
</tr>
<tr>
<td>C10 – Epiglottic Movement</td>
<td>$r = .348, p = .021^*$</td>
</tr>
<tr>
<td>C5 – Oral Residue</td>
<td>$r = .319, p = .035^*$</td>
</tr>
<tr>
<td>C16 – Pharyngeal Residue</td>
<td>$r = .285, p = .061$</td>
</tr>
<tr>
<td>C13 – Pharyngeal Contraction</td>
<td>$r = .260, p = .088$</td>
</tr>
<tr>
<td>C4 – Bolus Transport / Lingual Motion</td>
<td>$r = .226, p = .139$</td>
</tr>
<tr>
<td>C2 – Tongue Control During Bolus Hold</td>
<td>$r = .139, p = .367$</td>
</tr>
<tr>
<td>C7 – Soft Palate Elevation</td>
<td>$r = .110, p = .476$</td>
</tr>
<tr>
<td>C1 – Lip Closure</td>
<td>$r = -.068, p = .661$</td>
</tr>
<tr>
<td>C6 – Initiation of Pharyngeal Swallow</td>
<td>$r = .045, p = .771$</td>
</tr>
<tr>
<td>C14 – Pharyngoesophageal Segment Opening</td>
<td>$r = .040, p = .795$</td>
</tr>
</tbody>
</table>

Table 3 Correlations between individual MBSImP components and EAT-10 scores.

** The double asterisk denotes statistical significance at the 0.01 level.

* The single asterisk denotes statistical significance at the 0.05 level.
Individual Findings

Two participants in this study stand out as having a large discrepancy between EAT-10 score and combined oral and pharyngeal MBSImP scores. Consistent with previous literature (Hughes et al., 2000), the one patient in this sample who had a history of nasopharyngeal cancer had one of the largest discrepancies between self-ratings of impairment (EAT-10 = 12), reported oral intake (FOIS = 6) and physiologic findings (combined oral and pharyngeal MBSImP scores = 35) indicating that perhaps nasopharyngeal cancer patients’ perception of function do not correlate with findings on MBS. In addition, the youngest participant in this study had a large discrepancy between the EAT-10 score (38) and combined oral and pharyngeal MBSImP scores (12) perhaps indicating an age or generational component to these findings.

FOIS

The relationship between the EAT-10 and the FOIS was investigated using Spearman’s correlation coefficient. As shown in Figure 4, the relationship between the EAT-10 and the FOIS revealed a strong negative correlation ($r = -0.509; p < 0.01$). Moderate negative correlations between the FOIS and the combined oral and pharyngeal MBSImP scores ($r = -0.394; p < 0.01$) and the FOIS and the pharyngeal impairment score ($r = -0.387; p < 0.01$) are shown in Figures 5 and 6 respectively. The correlation between the FOIS and the oral phase was not statistically significant ($r = -0.268; p = 0.79$) as shown in Figure 7.
Figure 4: Correlation between the EAT-10 and the FOIS.

Figure 5: Correlation between the FOIS and the combined oral and pharyngeal impairment scores.
Figure 6: Correlation between the FOIS and the pharyngeal impairment scores.

Figure 7: Correlation between the FOIS and the oral impairment scores.
A bimodal distribution of FOIS scores was obtained, as shown in Figure 8. Therefore, the FOIS scores were divided to assess differences in patient-reported swallowing impairment score for participants who were tube dependent versus those who had total oral intake. Tube dependent was defined as those who obtained a FOIS score of \( \leq 3 \) (\( N = 17 \), mean = 1.88 \( \pm \) 0.49). Participants with total oral intake were defined as those who obtained a FOIS score of \( \geq 4 \) (\( N = 27 \), mean = 6 \( \pm \) 0.68). An independent samples \( t \)-test, which did not assume equal variances due to the large discrepancy in the sample standard deviations, was conducted. Participants who were tube dependent had a significantly higher mean EAT-10 score (\( M = 26.47 \), \( SD = 8.52 \)) compared to the mean EAT-10 score for those with total oral intake (\( (M = 18.59 \), \( SD = 10.49 \)), \( t(39) = 2.72 \), \( p = 0.01 \)) as shown in Figure 9.
Figure 8: Distribution of FOIS scores.

Figure 9: Mean EAT-10 scores for participants who are tube dependent versus total oral intake.
PAS

The relationship between the EAT-10 and the PAS was investigated using Spearman’s correlation coefficient and revealed a moderate positive correlation \( r = 0.349; p < 0.05 \) as shown in Figure 10. Strong positive correlations between the PAS and the combined oral and pharyngeal MBSImP scores \( (r = .773; p < 0.01) \) and the PAS and the pharyngeal impairment score \( (r = .786; p < 0.01) \) are shown in Figures 11 and 12, respectively. Figure 13 displays a strong positive correlation between the oral impairment scores and PAS \( (r = .500; p < 0.01) \). The relationship between the PAS and FOIS was also investigated and revealed a moderate negative correlation \( r = -0.313; p < 0.05 \), as shown in Figure 14.
Figure 10: Correlation between the EAT-10 and the PAS.

Figure 11: Correlation between the PAS and the combined oral and pharyngeal impairment scores.
Figure 12: Correlation between the PAS and the pharyngeal impairment scores.

Airway Safety & Pharyngeal Impairment

\[ r = 0.786; p < 0.01 \]

Figure 13: Correlation between the PAS and the oral impairment scores.

Airway Safety & Oral Impairment

\( r = 0.500; p < 0.01 \)
A bimodal distribution in PAS scores, as shown in Figure 15, was obtained. Therefore, the PAS scores were further divided to assess differences in patient-reported swallowing impairments for “safe” versus “unsafe” swallower. Safe swallower were defined as those who obtained a PAS score of ≤ 2 (N = 15, mean = 1.7 ± .46). Unsafe swallower were defined as those who obtained a PAS score of ≥ 3 indicative of penetration and/or aspiration (N = 29, mean = 6.9 ± 1.7). An independent samples t-test, which did not assume equal variances due to the large discrepancy in the sample standard deviations, was conducted. Safe swallower had an overall lower mean EAT-10 score (M = 16.20, SD =
12.14) than the mean EAT-10 score for unsafe swallowers ((\(M = 24.25, SD = 8.32\)), \(t(21) = -2.36, p = .03\)) as shown in Figure 16.

Figure 15: Distribution of PAS scores.
Reliability

Inter- and intra-rater reliability of the 16 components of the MBSImP that assess the oral and pharyngeal phases of swallowing were analyzed using the ICC with an absolute agreement definition. Intra-judge reliability for MBSImP ratings using ICC was calculated for 100% of the measures made by the primary investigator and demonstrated high consistency of repeated measures ICC = 0.99 [95% CI .998, .999]. Inter-judge reliability for the MBSImP ratings for three SLPs compared to the primary investigator were calculated and displayed in Table 4.
<table>
<thead>
<tr>
<th></th>
<th>Intraclass Correlation</th>
<th>95% Confidence Interval</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rater 1</td>
<td>.985</td>
<td>[.957, .995]</td>
<td>Good</td>
</tr>
<tr>
<td>Rater 2</td>
<td>.997</td>
<td>[.992, .999]</td>
<td>Good</td>
</tr>
<tr>
<td>Rater 3</td>
<td>.908</td>
<td>[.739, .969]</td>
<td>Good</td>
</tr>
</tbody>
</table>

Table 4 – Inter-rater reliability for three independent raters compared to the primary investigator. ICC strengths are based on $< 0.5 =$ poor, $0.5 – 0.74 =$ moderate, $> 0.75 =$ Good (Portney & Watkins 2000).
Chapter 5: Discussion

Dysphagia is a common consequence of HNC across all time intervals of care (initial diagnosis, acute side effects of treatment, and long-term response). With the rise in incidence of oropharyngeal cancer and the shift in patient demographics, individuals are presenting with HNC at a much earlier age than ever seen before. Management of dysphagia, a life-long, long-term side effect of cancer treatment, has evolved and now has a whole new meaning as individuals in their fourth, fifth, and sixth decades of life are requiring swallow assessment, rehabilitation, and long-term monitoring of swallowing function to prevent life threatening consequences, such as aspiration pneumonia. Identification of a validated, easy-to-administer tool that can be utilized with this patient population can assist with timely recognition and management of dysphagia symptoms.

The current study analyzed the possible relationships between two rating scales associated with swallowing function and objective findings of swallow physiology of individuals with dysphagia as a result of HNC. Overall, significant correlations between the EAT-10, FOIS, PAS, and combined oral and pharyngeal MBSImP scores ($r = 0.46, -0.39, \text{ and } 0.77$ respectively) were observed for the HNC population.

The primary aim of the current study was to assess the relationship between patient-and clinician-ratings of swallowing function in individuals with HNC. This is the first study to show a moderate positive correlation between a patient self-report of swallowing
impairment (EAT-10) and objective, clinician-ratings of swallowing function (MBSImP) ($r = .459, p = 0.002$). Two previous studies have examined the relationship between patient- and clinician-ratings of swallowing function in individuals with HNC and found no significant correlations (Kendall et al., 2014; Rogus-Pulia et al., 2014) other than that individuals with HNC can identify an overall deterioration in swallowing function (Pauloski et al., 2002; Rogus-Pulia et al., 2014). Kendall and colleagues (2014) found that the MD Anderson Dysphagia Inventory (Chen et al., 2001) and The University of Washington Swallowing Quality of Life Questionnaire (Thomas et al., 2008) did not significantly correlate with objective measures of swallowing physiology (Kendall et al., 2014). Rogus-Pulia and colleagues (2014) described a novel series of twelve questions administered via a Likert-scale and found that patients treated with chemoradiation for HNC lacked awareness of their dysphagia symptoms (Rogus-Pulia et al., 2014).

The current study identified five symptom-specific issues from the EAT-10 (my swallowing problem interferes with my ability to go out for meals; swallowing liquids takes extra effort; swallowing solids takes extra effort; I cough when I eat; swallowing is stressful) (ranging from $r = 0.30$ to $r = 0.44$, $p < .05$) and one sign of dysphagia (my swallowing problem has caused me to lose weight) ($r = 0.35$, $p < .05$) that significantly correlated with physiological findings. One consistency between the current study and Rogus-Pulia et al. (2014) is that the question related to food sticks in my throat did not correlate with physiologic swallowing impairment ($r = 0.05$, $p = 0.74$). This may be indicative of the neurosensory deficits and reduced awareness of pharyngeal residue often seen with this
population (Nguyen et al., 2004).

There were eight specific components of the MBSImP that significantly correlated with the EAT-10 (ranging from \( r = 0.32 \) to \( r = 0.49, p < .05 \)). Interestingly, the two physiologic components on the MBSImP that correlated strongest with EAT-10 scores were laryngeal elevation \( (r = .486, p = .001) \) and base of tongue retraction \( (r = .439, p = .003) \). Previous literature has shown impaired base of tongue retraction and reduced hyolaryngeal elevation to be the two most salient features of dysphagia following head and neck radiation therapy due to fibrotic changes at the muscular level, which impacts muscle contraction, range of motion, and overall swallowing function (Logemann et al., 2008). This suggests that reported dysphagia via the EAT-10 might act as an indicator of the onset of muscle fibrosis, resulting in reduced function of the head and neck musculature. This hypothesis is also supported by the correlation between perceived effort \( (swallowing \text{ liquids takes extra effort and swallowing solids takes extra effort}) \), indicating neuromuscular weakness, and physiologic findings. However, given that these correlations were only moderate, other factors might play a role, warranting further investigation.

The current study also aimed to determine the relationship between patient-rated swallowing function and clinician-rated airway safety. A moderate positive correlation between the EAT-10 and the PAS \( (r = 0.349, p < 0.05) \) was found within this convenience sample. Airway safety is dependent upon adequate swallowing function and is therefore interconnected with swallowing impairment. In addition, participants who did not aspirate or penetrate had an overall lower mean EAT-10 score \( (M = 16.20, SD = 12.14) \) than participants
who did penetrate or aspirate \((M = 24.25, SD = 8.32)\), \(t(21) = -2.36, p = .03\). Within this study the EAT-10 was shown to have moderate correlations with two independent, though related, measures of swallowing impairment, the MBSImp and the PAS.

An additional aim of the current study was to assess the relationship between patient-rated swallow function and clinician rating of functional oral intake in individuals with HNC. Findings from this study revealed a strong negative correlation between the EAT-10 and the FOIS \((r = -0.509; p < 0.01)\). Specifically, individuals with higher complaints of dysphagia tended to have reduced oral intake as compared to those with less dysphagia complaints. This is consistent with the literature, which has shown pathophysiology related to swallowing function (impaired lingual strength and mobility) correlates with reduced dietary intake and aspiration (Butler et al., 2011; Lazarus et al., 2000). In addition, participants who were tube dependent had a significantly higher mean EAT-10 score \((M = 26.47, SD = 8.52)\) compared to the mean EAT-10 score for those with total oral intake \((M = 18.59, SD = 10.49), t(39) = 2.72, p = 0.01\).

Additional findings from the current study include the relationship between clinician-rated levels of oral intake and clinician-rated measures of swallowing function, including airway safety. Specifically, the FOIS was found to have a moderate negative correlation with the combined oral and pharyngeal \((r = -0.394; p < 0.01)\) and pharyngeal only \((r = -0.387; p < 0.01)\) components of the MBSImp as well as with the PAS \((r = -0.313; p < 0.05)\). Overall, individuals who reported increased difficulty swallowing via higher EAT-10 scores presented with increased swallowing impairment scores and increased penetration-aspiration as
compared to those with lower EAT-10 scores. Simultaneously, those with lower FOIS ratings revealed higher swallowing impairment scores on average. These findings suggest the EAT-10 and the FOIS may be reasonable outcome measures to use when treating and monitoring progression of dysphagia throughout the continuum of care of a HNC patient.

Consistent with findings from Pauloski and colleagues (2001), pharyngeal impairment had more of an impact on patient-reported dysphagia than oral impairment. Oral impairment scores alone did not significantly correlate with the EAT-10 ($r = .265; p = .082$) or the FOIS ($r = -0.268; p = .079$). These findings may be a result of the small sample of oral cavity cancer patients ($n = 4$) within this study. However, oral impairment scores did strongly correlate with the PAS ($r = .500; p < 0.01$), demonstrating a relationship between oral impairment and airway safety. This finding is consistent with the literature as oral phase functioning has been previously correlated with lingual strength (Lazarus et al., 2000) and reduced lingual strength has been shown to correlate with aspiration (Butler et al., 2011; Lazarus et al., 2000).

Conclusions

Findings from the current study are consistent with previous findings that individuals with HNC can perceive difficulty with swallowing function (Pauloski et al., 2002; Rogus-Pulia et al., 2014). However, this is the first study to identify a significant relationship between a dysphagia-specific, patient-reported outcome measure and physiological findings on MBS. Several patient-reported outcome measures exist for use with HNC patients; however, none have been deemed the gold standard in terms of being clinically meaningful.
or scientifically robust (Pusic et al., 2007). In the clinical setting, the consistent use of outcome measures to document the need for therapeutic services is becoming more prevalent as insurance companies dictate documentation requirements and rely on outcome measures to approve or deny services.

Given the results of the current study, the EAT-10 and FOIS are reasonable outcome measures to choose, administer, and document in the clinical setting for HNC-induced dysphagia. In addition, these specific outcome tools can assist health care providers in determining the appropriateness for instrumental swallowing assessments. Although the current study suggests that the EAT-10 may have relevance in the clinical and research settings for this population, caution is advised given that findings in this study showed only moderate correlations suggesting patient-report of swallowing impairment cannot be relied upon solely for identifying oropharyngeal dysphagia.

**Limitations**

There are several limitations to this study. The participants were heterogeneous in terms of tumor site and treatment modality. In addition, cancer staging, recurrence rates, time at which MBS was performed in relation to cancer treatment, and other medical comorbidities were not obtained and analyzed. Cancer stage has been shown to correlate with functional outcomes of tongue strength, swallowing ability and quality of life measures (Lazarus et al., 2013). Data regarding cancer staging and recurrence would allow for group analysis in terms of the size and extent of the primary tumor, including whether or not cancer metastasis was present. Characteristics of dysphagia secondary to HNC are dependent
primarily upon tumor size and the presence or absence of metastatic neck disease (Logemann et al., 2008). Data regarding when the MBS was performed in relation to cancer treatment and the participant’s medical comorbidities would allow for control over variables, which impact swallowing function. Specifically, five participants in the current study had not yet received cancer treatment and therefore had the impact of mass effect on swallowing function without the sequela of cancer treatment. An equal number of participants in each stage of care would allow for a between-groups analysis of participants before and after specific cancer treatment modalities. In addition, all data from each participant were obtained at a single time point. Obtaining pre- and post-treatment data for each of the outcome measures tested would strengthen the findings and allow for generalization regarding the concept of capturing a change in swallowing function over time.

**Future Studies**

Future studies should aim to recruit an equal number of participants for all tumor sites and stages in order to conduct between-groups analyses. In addition, a longitudinal approach, following participants over a period of time, would support the use of these outcome tools to be used repeatedly in the clinical setting as a means of monitoring swallowing function. Obtaining lingual strength measurements at each data collection point would also strengthen the findings, as lingual strength has been shown to predict functional outcomes related to swallowing (Butler et al., 2011; Lazarus et al., 2000). The participant’s ability to read and independently complete the EAT-10 was based solely on the participant’s verbal report of literacy. Cognitive testing to determine the participant’s ability to participant in the current
study would strengthen the reliability of the results. In addition, levels of depression were not assessed and could impact results of a self-report regarding functional swallowing status. Swallowing function and depression have been shown to correlate previously (Lin, Starmer, & Gourin, 2012). Lastly, the current study was conducted at one medical center. In order to increase external validity of findings, a multicenter trial to determine the relationship between patient self-report and physiological findings of swallowing function using these outcome tools would be warranted.


References


Appendix A: Eating Assessment Tool 10 (Belafsky et al., 2008)
<table>
<thead>
<tr>
<th>Circle the appropriate responses</th>
<th>0 = no problem</th>
<th>4 = severe problem</th>
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<tbody>
<tr>
<td>1. My swallowing problem has caused me to lose weight.</td>
<td>0 1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>2. My swallowing problem interferes with my ability to go out for meals.</td>
<td>0 1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>3. Swallowing liquids takes extra effort.</td>
<td>0 1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>4. Swallowing solids takes extra effort.</td>
<td>0 1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>5. Swallowing pills takes extra effort.</td>
<td>0 1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>6. Swallowing is painful.</td>
<td>0 1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>7. The pleasure of eating is affected by my swallowing.</td>
<td>0 1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>8. When I swallow food sticks in my throat.</td>
<td>0 1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>9. I cough when I eat.</td>
<td>0 1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>10. Swallowing is stressful.</td>
<td>0 1 2 3 4</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
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Appendix B: Functional Oral Intake Scale (Crary et al., 2005)
TUBE DEPENDENT (levels 1-3)

1 No oral intake

2 Tube dependent with minimal/inconsistent oral intake

3 Tube supplements with consistent oral intake

TOTAL ORAL INTAKE (levels 4-7)

4 Total oral intake of a single consistency

5 Total oral intake of multiple consistencies requiring special preparation

6 Total oral intake with no special preparation, but must avoid specific foods or liquid items

7 Total oral intake with no restrictions
Appendix C: The MODIFIED BARIUM SWALLOW IMPAIRMENT PROFILE:
Components, Scores, and Score Definitions

ORAL Impairment
Component 1—Lip Closure
0 = No labial escape
1 = Interlabial escape; no progression to anterior lip
2 = Escape from interlabial space or lateral juncture; no extension beyond vermilion border
3 = Escape progressing to mid-chin
4 = Escape beyond mid-chin

Component 2—Tongue Control During Bolus Hold
0 = Cohesive bolus between tongue to palatal seal
1 = Escape to lateral buccal cavity/floor of mouth (FOM)
2 = Posterior escape of less than half of bolus
3 = Posterior escape of greater than half of bolus

Component 3—Bolus Preparation/Mastication
0 = Timely and efficient chewing and mashing
1 = Slow prolonged chewing/mashing with complete re-collection
2 = Disorganized chewing/mashing with solid pieces of bolus unchewed
3 = Minimal chewing/mashing with majority of bolus unchewed

Component 4—Bolus Transport/Lingual Motion
0 = Brisk tongue motion
1 = Delayed initiation of tongue motion
2 = Slowed tongue motion
3 = Repetitive/disorganized tongue motion
4 = Minimal to no tongue motion

Component 5—Oral Residue
0 = Complete oral clearance
1 = Trace residue lining oral structures
2 = Residue collection on oral structures
3 = Majority of bolus remaining
4 = Minimal to no clearance

Location
A = Floor of mouth (FOM)
B = Palate
C = Tongue
D = Lateral sulci

Component 6—Initiation of Pharyngeal Swallow
0 = Bolus head at posterior angle of ramus (first hyoid excursion)
1 = Bolus head in valleculae
2 = Bolus head at posterior laryngeal surface of epiglottis
3 = Bolus head in pyriforms
4 = No visible initiation at any location

PHARYNGEAL Impairment
Component 7—Soft Palate Elevation
0 = No bolus between soft palate (SP)/pharyngeal wall (PW)
1 = Trace column of contrast or air between SP and PW
2 = Escape to nasopharynx
3 = Escape to nasal cavity
4 = Escape to nostril with/without emission

Component 8—Laryngeal Elevation
0 = Complete superior movement of thyroid cartilage with complete approximation of arytenoids to epiglottic petiole
1 = Partial superior movement of thyroid cartilage/partial approximation of arytenoids to epiglottic petiole
2 = Minimal superior movement of thyroid cartilage with minimal approximation of arytenoids to epiglottic petiole
3 = No superior movement of thyroid cartilage

Component 9—Anterior Hyoid Excursion
0 = Complete anterior movement

69
Component 10—Epiglottic Movement
0 = Complete inversion
1 = Partial inversion
2 = No inversion
Component 11—Laryngeal Vestibular Closure – Height of Swallow
0 = Complete; no air/contrast in laryngeal vestibule
1 = Incomplete; narrow column air/contrast in laryngeal vestibule
2 = None; wide column air/contrast in laryngeal vestibule
Component 12—Pharyngeal Stripping Wave
0 = Present – complete
1 = Present - diminished
2 = Absent
Component 13—Pharyngeal Contraction (A/P VIEW ONLY)
0 = Complete
1 = Incomplete (Pseudodiverticulae)
2 = Bilateral Bulging
3 = Unilateral Bulging
Component 14—Pharyngoesophageal Segment Opening
0 = Complete distension and complete duration; no obstruction of flow
1 = Partial distension/partial duration; partial obstruction of flow
2 = Minimal distension/minimal duration; marked obstruction of flow
Component 15—Tongue Base (TB) Retraction
0 = No contrast between TB and posterior pharyngeal wall (PW)
1 = Trace column of contrast or air between TB and PW
2 = Narrow column of contrast or air between TB and PW
3 = Wide column of contrast or air between TB and PW
4 = No visible posterior motion of TB
Component 16—Pharyngeal Residue
0 = Complete pharyngeal clearance
1 = Trace residue within or on pharyngeal structures
2 = Collection of residue within or on pharyngeal structures
3 = Majority of contrast within or on pharyngeal structures
4 = Minimal to no pharyngeal clearance

Location
A = Tongue Base
B = Vallecule
C = Pharyngeal wall
D = Aryepiglottic folds
E = Pyriform sinuses
F = Diffuse (>3 areas)
Appendix D: Penetration-Aspiration Scale (Rosenbek et al., 1996)
Score Description of Events

1. Material does not enter airway

2. Material enters the airway, remains above the vocal folds, and is ejected from the airway.

3. Material enters the airway, remains above the vocal folds, and is not ejected from the airway.

4. Material enters the airway, contacts the vocal folds, and is ejected from the airway.

5. Material enters the airway, contacts the vocal folds, and is not ejected from the airway.

6. Material enters the airway, passes below the vocal folds, and is ejected into the larynx or out of the airway.

7. Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort.

8. Material enters the airway, passes below the vocal folds, and no effort is made to eject.
Appendix E: Consent to Participate in Research Form
The Ohio State University Consent to Participate in Research

Study Title: Assessment of the relationship between patient and clinician ratings of swallowing function in individuals with head and neck cancer.

Principal Investigator: Ricardo Carrau, MD

Sponsor: None

• This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

• Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

• You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

• You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?
This study is being done to determine if there is a relationship between a 10 question patient survey, the EAT-10, and swallowing measures obtained during a clinical swallowing test, the Modified Barium Swallow (MBS), which is performed by a speech language pathologist and a radiology resident or technician. Comparing the information collected from the survey and MBS test may show if the swallowing difficulties reported by an individual are similar to the results obtained during clinical testing. Hopefully, the results of this study will provide guidance to medical providers on how and when to treat swallowing difficulties.
2. **How many people will take part in this study?**
   About 45 people will take part in this study.

3. **What will happen if I take part in this study?**
   Once you are enrolled in this study you will be asked to arrive 20 minutes prior to your scheduled modified barium swallow study. This is 5 minutes earlier than required for a typical appointment. During that time you will complete a questionnaire consisting of 10 questions related to your swallowing. Information from your medical records will also be collected so that we can compare the results from your swallowing tests to the information that you provide in the survey. This information will be stored in a secure, password protected computer database.

4. **How long will I be in the study?**
   The study related time will last between 2 and 20 minutes, the time needed to complete the survey. Your information may be stored in the database for several years, as time will be needed to collect and review all of the data.

5. **Can I stop being in the study?**
   You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. **What risks, side effects or discomforts can I expect from being in the study?**
   There is a slight risk that your information may be seen by someone not associated with the study (breach of confidentiality), but this risk will be reduced by storing your information on a secure computer and limiting access to the information to only people associated with the study. There are no other anticipated risks, side effects, or discomforts to being in this study.

7. **What benefits can I expect from being in the study?**
   You may or may not personally benefit from participating in this study. This project has the potential to identify an easy, low cost means for tracking your swallowing abilities throughout your care. However, you may not benefit at all from being in this study.

8. **What other choices do I have if I do not take part in the study?**
   You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.
9. **Will my study-related information be kept confidential?**

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):
- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician’s office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. **What are the costs of taking part in this study?**

There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further.

11. **Will I be paid for taking part in this study?**

You will not be paid for taking part in this study.

12. **What happens if I am injured because I took part in this study?**
If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center. The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?
If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?
For questions, concerns, or complaints about the study you may contact Loni Arrese at 614.293.7442.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Loni Arrese at 614.293.7442.
Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

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Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

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<th>Printed name of person obtaining consent</th>
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Witness (es) - *May be left blank if not required by the IRB*

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